A Phase I, Pilot Study of Human Embryonic Stem Cell-Derived Cardiomyocytes in PaTients with ChrOnic Ischemic Left VentRicular Dysfunction (HECTOR)

Grant Award Details

A Phase I, Pilot Study of Human Embryonic Stem Cell-Derived Cardiomyocytes in PaTients with ChrOnic Ischemic Left VentRicular Dysfunction (HECTOR)

Grant Type: Clinical Trial Stage Projects

Grant Number: CLIN2-12735

Project Objective: Conduct a first in human clinical trial of hESC-CM in a chronic heart failure population to determine the safety and feasiblity of the approach as well as the phase 2 recommended dose.

Investigator:

Name:	Joseph Wu
Institution:	Stanford University
Type:	PI

Disease Focus: Heart Disease, Heart failure

Human Stem Cell Use: Embryonic Stem Cell

Award Value: $6,987,507

Status: Active

Grant Application Details

Application Title: A Phase I, Pilot Study of Human Embryonic Stem Cell-Derived Cardiomyocytes in PaTients with ChrOnic Ischemic Left VentRicular Dysfunction (HECTOR)

Public Abstract:

Therapeutic Candidate or Device

The therapeutic candidate is human embryonic stem cell-derived cardiomyocytes (hESC-CMs) as a new therapy for chronic ischemic cardiomyopathy patients

Indication

hESC-CMs will be indicated for treatment of heart failure (HF) and for preventing progression to HF in patients with chronic ischemic cardiomyopathy.

Therapeutic Mechanism

There are two commonly accepted mechanisms by which these hESC-CMs can impact the target indication: (i) injected cells release paracrine factors that act on the myocardium, resulting in improved angiogenesis and (ii) injected cells engraft in the myocardium, resulting in improved cardiac function.

Unmet Medical Need

Ischemic heart disease accounts for 60% of HF. With limited availability of donor hearts and a bleak prognosis, new therapeutic strategies are needed. This trial will test the safety and feasibility of administering hESC-CMs as a therapy for treating chronic ischemic cardiomyopathy.

Project Objective

Determine safety and feasibility in Phase I trial.

Major Proposed Activities

- Prepare for trial initiation
  - Complete regulatory approvals
  - Finalize clinical study protocol, informed consent form, IRB approval
  - Relevant training
- Recruit and randomize participants
  - Enroll first participant
  - Recruit the target sample size
  - Follow-up visit of the enrolled participants
- Data collection and management
  - Primary and secondary endpoint analyses
  - Final study report and manuscript submission
  - Results reporting

Statement of Benefit to California:

As the most populous state in the nation, California bears a substantial fraction of the social and economic costs associated with heart disease. Stem cell therapy has emerged as a promising candidate for treating ischemic heart disease. This program may pave the way for a promising new therapy to treat Californians with heart failure. In addition, this program will further enhance California's continuing prominence as a leader in the promising field of stem cell research and therapeutics.

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